

**REMARKS**

The Office Action mailed on July 09, 2007, has been reviewed and the comments of the Patent and Trademark Office have been considered. Prior to this paper, claims 1-58 and 60-136 were pending, with claims 10-35, 54-105, 119, 120, 123-126 and 129-136 being withdrawn. By this paper, Applicant cancels no claim, and adds claims 137-140. Therefore, claims 1-58 and 60-140 are now pending.

Applicant respectfully submits that the present application is in condition for allowance for at least the reasons that follow.

**Acknowledgement of References Cited**

Applicant respectfully requests that the references listed on the forms submitted with the Information Disclosure Statement filed by Applicant on June 13, 2007, be initialed by an examiner and a copy of the form showing the initialization be provided to Applicant's agent. Additional copies of the Forms PTO/SB/08 are enclosed for the PTO's convenience in Appendix A, while a copy of the stamped postcard evincing submittal of those documents and the accompanying references is provided in Appendix B.

Pursuant to the telephone interview of September 26, 2007, if the PTO cannot find the foreign references and the non-patent literature submitted with the IDS of June 13, 2007, Applicant will resubmit copies of the missing documents as necessary. Applicant submits that he is entitled to the filing date of the IDS in which these documents were first cited, and thus no fees will be necessary, and that the documents should be considered as if they were submitted on June 13, 2007, which they were.

**Specification Objections**

The Specification is objected to as containing informalities. In response, in order to advance prosecution, and without prejudice or disclaimer, Applicant hereby amends the specification as seen above, and requests reconsideration in view of those amendments.

Applicant thanks Examiner Sasan for taking the time to recommend changes to the specification to alleviate the objections.

**Claim Rejections Under 35 U.S.C. §103(a)**

In the Office Action, claims 1, 5-9, 36, 41-48, 50-53, 106-118, 121-122 and 127-128 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Takaharu (JP 2000-239159), while claims 2 and 38 stand rejected under the same statute in view of the combination of Takaharu with Lebrun (U.S. Patent No. 4,940,499), and claims 3-4, 37 and 39-40 are rejected in view of the just-mentioned combination when further combined with Story (U.S. 5,738,871). Applicant respectfully traverses the rejection as to the claims above, and submits that these claims are allowable for at least the following reasons.

Applicant relies on MPEP § 2143, which states that:

[t]o establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

It is respectfully submitted that at least the first and second requirements of MPEP §2143 have not been met in the prosecution of this application.

Contrary to MPEP §2143, the examiner has not satisfied the basic requirements for establishing a *prima facie* case of obviousness. In particular, the examiner points to no prior art evidencing motivation for the person of ordinary skill to have modified the primary

reference (Takaharu). Rather, the examiner's rationale for *why* the skilled artisan would have undertaken such modification is logically circular, relies on impermissible hindsight, and, if anything, **validates the proposition that the skilled artisan would not have effected the modification in question.** For example, the record is devoid of any reason why one of ordinary skill would have modified Takaharu to obtain a feature -- that of a “separated state visibly recognizable from the outside of the capsule preparation” -- when that very feature, central to Takaharu, appears in the reference without modification. This absence of modification is not surprising, moreover, as the examiner's ad hoc proposal changes the principle of operation of the reference, which obviates any reasonable expectation of success for the posited modification. Indeed, the primary reference teaches away from the present invention, which renders the allegation of obviousness wholly untenable under Section 103.

#### Lack of Suggestion or Motivation to Modify or Combine the References

MPEP §2142, entitled “Legal Concept of *Prima Facie* Obviousness,” states that “impermissible hindsight must be avoided and the legal conclusion must be reached on the basis of the facts gleaned from the prior art.” In this regard, the Office Action asserts that it would have been obvious to modify Takaharu because, quoting from the abstract of Takaharu, “the separated state is visibly recognizable from the outside of the capsule preparation.” (Office Action, paragraph spanning pages 4 and 5.) Applicant submits that this motivation sounds in clear impermissible hindsight, and, in fact, the logic proffered in the Office Action leads the ordinary artisan to implement the teachings of Takaharu exactly as taught, not to modify the teachings of Takaharu.

The Office Action asserts that language from Takaharu, which explicitly details the alleged result of implementation of Takaharu (*i.e.*, visible separation of the ingredients), suggests to the ordinary artisan to modify Takaharu. This is not logical, as is readily seen by asking the following question: would one of ordinary skill in the art modify Takaharu to obtain a capsule where “the separated state is visibly recognizable from the outside of the capsule” when Takaharu purports to teach a capsule that does exactly that, without

modification? That is, to the extent that the ordinary artisan was seeking a capsule in which different ingredients are readily identifiable in a separate state, the ordinary artisan would have found Takaharu and stopped there. The only way the PTO can arrive at the present invention is by starting out at the invention as claimed and working backwards, which is impermissible hindsight, a process forbidden by MPEP §2142.

Put another way, the Takaharu references presents an internally consistent teaching of a capsule design that provides a feature that is assumed *arguendo* to be desirable in the art (*i.e.*, readily identifiable ingredients in a capsule in a separate state). Modifying Takaharu as proffered in the Office Action would have no particular effect in the art. The proffered motivation to modify Takaharu is an omnibus motivation – it would have been obvious to modify Takaharu to have structure X to obtain feature Y because Takaharu teaches structure Z to achieve feature Y. Based on such logic, any improvement over Takaharu would automatically be obvious, a result that is inconsistent with 35 U.S.C. §103. Takaharu provides nothing in the way of predictive value that the ordinary artisan (who is by definition a non-innovator) would have sought to modify Takaharu in the proffered manner. It is respectfully submitted that hindsight forms the underlying basis for the rejection.

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Impermissible hindsight issues aside, the real issue here is whether or not the present invention represents a change from Takaharu that is the work of the innovator, as opposed to the work of the mere ordinary artisan. Applicant submits that the proffered motivation answers this question in the affirmative. The ordinary artisan does not seek to modify a prior art device to do exactly the same thing that the prior art device already purports to do (*i.e.*, to have a separated state that is visibly recognizable from the outside of the capsule). To the contrary, it is the innovator who modifies the prior art to do what the prior art already does (for various reasons that are not obvious). Accordingly, if the ordinary artisan was asked for a capsule in which a separated state was visible from the outside, the ordinary artisan would simply provide a capsule according to Takaharu. Only the innovator would seek to modify Takaharu.

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Another way that the lack of motivation to modify Takaharu to arrive at the present invention is demonstrated is by analyzing the circular nature of the proffered motivation (*i.e.*, to obtain a feature that Takaharu already has). In this regard, it is respectfully submitted that no proper rationale as to why one of ordinary skill in the art would have modified Takaharu has yet been identified by the PTO. True, the Office Action states a result of modifying Takaharu (a result that may also be achieved without modifying Takaharu). However, Applicant respectfully submits that a result is not the same as *a reason why* one of ordinary skill in the art would have been motivated to modify the prior art. If motivation to combine references to establish a *prima facie* case of obviousness could merely be satisfied by a result-oriented analysis of the prior art, the first requirement (and second requirement) of MPEP §2143 would be completely vitiated. This is because by identifying references that teach each individual element of a claimed invention, implementation of the teachings of the cited references almost always necessarily provides results according to a given invention under examination. Indeed, such an analysis relies on impermissible circular reasoning.

In contrast to the result-oriented analysis proffered in the Office Action, the MPEP specifically states that “the prior art must suggest the desirability of the claimed invention.” The Office Action, in relying only on results, does not identify where the prior art suggests the desirability of a capsule according to the independent claims. The analysis pursuant to the first requirement of MPEP §2143 sounds in circular reasoning.

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For motivation to modify or combine a reference to warrant a rejection sounding in obviousness, logically, there must be a cause-and-effect relationship between (i) the proffered motivation on the one hand and (ii) the proffered modification on the other hand. With this in mind, the Office Action asserts that the ordinary artisan would have been motivated to produce a capsule having a

plurality of ingredient phases because “Takaharu teaches that ‘the therapeutic effectiveness of the capsule is high (Detailed Description, [0026]).’ The incompatibility between the different drugs in the capsule is minimized. ‘Two or more sorts of drug effect components can be safely prescribed by one capsule’ (Detailed Description, [0027]).

(Office Action, page 4, third paragraph.) However, the cited language does not relate to the physical state of the plurality of ingredients in the capsule of Takaharu. True, the term “phase” is twice used in the machine translation of Takaharu at paragraph 0027 (although used nowhere in paragraph 0026). However, Applicant respectfully submits that the term “phase” is not used in Takaharu to construe the physical state of the ingredients. That is, the term “phase,” as used in Takaharu, does not refer to whether the ingredient is in a liquid, state, a solid state, etc. Indeed, at paragraph 0008 of the machine translation, Takaharu states that “it is desirable that each *two or more component phases* which constitute these drugs are in a liquid condition.” (Takaharu, paragraph 0008, emphasis added.) Accordingly, it is clear that the term “phase” does not relate to the physical state of the ingredients. Instead, the term is probably used to refer to the “discrete homogeneous part of a material system that is mechanically separable from the rest,” pursuant to the American Heritage Dictionary of the English Language “chemistry definition” of the term “phase,” which comports with the purported overall goal of Takaharu (to provide a capsule in which one may see the different ingredients separated from one another).<sup>1</sup>

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MPEP § 2143.01, subsection 6, states that “the proposed modification cannot change the principle of operation of a reference – If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. *In re Ratti*, 270 F.2d 810 (CCPA 1959).” In *Ratti*, the CCPA held that the “suggested combination of references would require a substantial reconstruction and redesign of the elements shown in the primary reference.” This substantial redesign would have resulted in changing a rigid seal to a resilient seal. Thus, a reference cannot be modified to render an invention obvious if the modification changes a principle of operation of the reference.

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<sup>1</sup> Indeed, paragraph 0008 of Takaharu (machine translation) goes on to state that “it is more desirable to have dissociated in the shape of a layer for every component phase in this case;” language that clearly comports with the “chemistry definition” of the term “phase.”

With the above in mind, it is respectfully submitted that because the teachings of Takaharu rely on differences between the specific gravities of the ingredients in the capsule to maintain the identifyability of the ingredients, substituting a multi-compartment arrangement for the specific gravity stratification of Takaharu would change the principle of operation of Takaharu. Because modifying Takaharu to utilize a multi-chamber arrangement changes the principle of operation of Takaharu, just as changing the rigid seal to a resilient seal was found to change the principle of operation in *Ratti*, “the teachings of [Takaharu] are not sufficient to render the claims *prima facie* obvious.” (MPEP § 2143.01, emphasis added.)

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MPEP § 2144.05(III), entitled Rebuttal Of *Prima Facie* Case Of Obviousness, states that a “*prima facie* case of obviousness may also be rebutted by showing that the art, in any material respect, teaches away from the claimed invention.” (MPEP § 2144.05(III), second paragraph, emphasis added, citations omitted.) As just noted, Takaharu specifically states that “it is desirable that each two or more component phases which constitute these drugs are in a liquid condition.” (Takaharu, paragraph 0008, emphasis added.) Applicant respectfully submits that to the extent that a case of obviousness has been established, that case is hereby rebutted, as Takaharu clearly teaches away from a capsule according to the present invention.

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**Claims 2 and 38:** Claims 2 and 38 recite a specific structure of the capsule according to the present invention vis-à-vis a cap and a base. The Office Action points to Lebrun as teaching this feature, and asserts as motivation to combine Lebrun with Takaharu, that “the sealing of the body and cap of the capsule ‘ensures positive retention of medicaments.’” This is another example of the evisceration of the first requirement of MPEP §2143 and the reliance on impermissible hindsight, where motivation to modify Takaharu to utilize allegedly known elements from another reference is based solely on the fact that the prior art allegedly teaches those known elements. That is, if the ordinary artisan had not been using the body and cap sealing arrangement of Lebrun in the first place in conjunction with the teachings of Takaharu (which he/she was not, as evinced by the need to combine the two references to formulate the preset rejection), the ordinary artisan would have not needed to “seal[] [the]

body and cap of the capsule [to] ensure[] positive retention of the medicaments.” Motivation to add features from the prior art cannot be based on a problem associated only with the addition of those features. There first must be motivation to modify the primary reference, else the motivation sounds in impermissible hindsight.

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**Claims 3-4, 37 and 39-40:** The Office Action recognizes that the alleged Takaharu-Lebrun combination fails to disclose or suggest the additional features of these claims (the features delta to claims 2 and 38 respectively), and introduces the Story reference to allegedly satisfy the deficiencies of the Takaharu-Lebrun combination. However, no motivation is provided at all to modify the Takaharu-Lebrun combination in accordance with the teachings of Story. Instead, the Office Action merely reiterates the alleged motivation to modify Takaharu with Lebrun, and makes the conclusory assertion that it would have been obvious to combine the Takaharu-Lebrun combination with Story. Conclusory assertions are not enough to satisfy the first requirement of MPEP §2143 vis-à-vis the establishment of a *prima facie* case of evidence. Sufficient motivation to modify the Takaharu-Lebrun combination to arrive at the inventions of claims 3, 4, 37 and 39-40 has not been proffered.

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In summary, because of the lack of suggestion or motivation in the prior art to modify Takaharu, the first requirement of MPEP § 2143 has not been met and, hence, a *prima facie* case of obviousness has not been established.

#### Lack of a Reasonable Expectation of Success

MPEP § 2143.02 permits references to be modified or combined to reject a claim as obvious only if there is a reasonable expectation of success. There is no evidence in the references, and certainly none identified in the Office Action, that one of ordinary skill in the art would have had a reasonable expectation of success in achieving Applicant’s invention by modifying Takaharu.

There is nothing in any of the cited references that amounts to even a modicum of predictive value that the ordinary artisan (who is by definition a non-innovator) would have had a reasonable belief that the proffered modification to Takaharu would have resulted in success. Indeed, the Office Action is completely silent in regard to the identification of a teaching *prior to Applicant's invention* whereby multi-compartment capsules successfully provided the features alleged in the Office Action in a manner consistent with the teachings of Takaharu. (Applicant notes that this example is simply a starting point for a showing of a reasonable expectation of success; more would be needed.) Thus, one of ordinary skill in the art would not have seen the proffered modification of Takaharu as resulting in a successful capsule. Because of this, the second criteria of MPEP § 2143 has not been met in the Office Action, and, therefore, a *prima facie* case of obviousness has therefore not been established for yet another reason.

### New Claims

As seen above, Applicant has added new claims 137-140. These claim depend either from non-withdrawn claims 1 and 36, and are allowable for at least the reason that claims 1 and 36 are allowable. Moreover, the claims recite that the ingredients in the different chambers are incompatible with one another, and claims 139 and 140 explicitly recite that the incompatibility is pharmaceutical incompatibility.

Takaharu explicitly and unambiguously teaches that the different ingredients must be compatible with one another. For example, paragraph 0026 of the machine translation states that “a capsule recipe person needs to cease to do the method of medicinal recipe which causes an incompatibility by taking the capsule concerning this invention.” (Emphasis added.) That is Takaharu explicitly warns that the ingredients must be compatible with one another, and that any activities related to the use of incompatible ingredients must “cease” when those activities involve the use of the “invention” (*i.e.*, the teachings) of Takaharu. Accordingly, these new claims are allowable for the additional reason that Takaharu explicitly teaches away from utilizing ingredients that are incompatible with one another.

**Rejoinder of the Withdrawn Claims**

Applicant notes that many of the withdrawn claims depend either directly or ultimately from claims 1 and 36. Applicant respectfully requests that these claims be rejoined and allowed due to their dependency from allowable claims. Applicant respectfully submits that no significant burden is placed on the PTO by rejoining and examining these claims. Indeed, such action is concomitant with the indication that “upon allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim.”

Further, the withdrawn independent claims should also be rejoined and allowed because the reasons that warrant the allowability of claims 1 and 36 apply with equal force to the other claims. Also, the method claims should be rejoined and allowed, pursuant to MPEP § 821.04 and *In re Ochiai*, 71 F.3d 1565, 37 USPQ2d 1127 (Fed. Cir. 1995), because MPEP § 821.04 states that “when a product claim is found allowable, applicant may present claims directed to the process of making and/or using the patentable product.”

**Conclusion**

Applicant believes that the present application is in condition for allowance. Favorable reconsideration is requested.

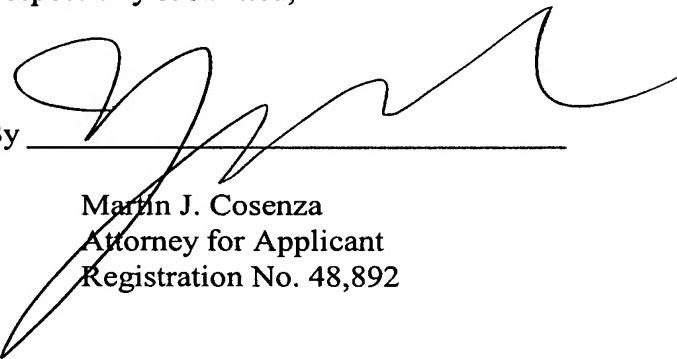
The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check or credit card payment form being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for

such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Examiner Sasan is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

Respectfully submitted,

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## APPENDIX A